REMARKS

The Restriction Requirement indicates that Group II, which includes claims 3-7 and 11-12, is "drawn to a polynucleotide and constructs containing it" (Office Action, September 16, 2003; page 2). Applicants respectfully point out that claims 11 and 12 are drawn, for example, to polynucleotides comprising "a polynucleotide sequence selected from the group consisting of SEQ ID NO:3-4," rather than to just a single polynucleotide. For at least this reason, this Restriction Requirement should be withdrawn.

Furthermore, the Restriction Requirement lists Groups I-XII, including claims 1-32. However, it appears that Group XII should properly include claim 33, which is drawn to methods of screening for modulators of expression of the polynucleotide of Group X, instead of claim 32. In addition, it appears that the subject matter of claim 32 (methods of using the polynucleotide of Group X to produce polypeptides) has not been included in any of the Groups set out in the Restriction Requirement. For at least these reasons, this Restriction Requirement should be withdrawn.

In response to the Restriction Requirement, Applicants hereby elect the claims of Group II (including claims 3-7 and 11-12), drawn to polynucleotides encoding SEQ ID NO:1, polynucleotides comprising SEQ ID NO:3, polynucleotide comprising SEQ ID NO:4, host cells, and vectors, with traverse. Applicants traverse the restriction requirement on the following grounds:

I. The Unity of Invention standard **must** be applied in national stage applications

Section 1850 of the Manual of Patent Examining Procedure (February 2003 revision of the original 8th edition) (hereinafter "M.P.E.P.") provides:

> . . . [W]hen the Office considers international applications . . . during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111. . .
>
> In applying PCT Rule 13.2 to . . . national stage applications under 35 U.S.C. 371, examiners should consider for unity of invention all the claims to different

> categories of invention in the application and permit retention in the same application for searching and/or preliminary examination, claims to the categories which meet the requirements of PCT Rule 13.2.

M.P.E.P. section 1893.03(d) reiterates the Patent Office's obligation to apply the Unity of Invention standard PCT Rule 13.2 instead of U.S. restriction/election of species practice:

> Examiners are reminded that unity of invention (not restriction) practice is applicable . . . in national stage applications submitted under 35 U.S.C. 371.

Specific provisions of the Administrative Regulations Under the PCT and the corresponding provisions of the M.P.E.P. strongly support a finding of unity of invention among all of the claims in the present case:

Unity of Invention is accepted as between claims to polypeptides and claims to the polynucleotides which encode them

Example 17, Part 2 of Annex B to the Administrative Regulations Under the PCT provides that unity of invention is accepted as between claims to polypeptides and claims to polynucleotides encoding those polypeptides. Those Examples are cited in M.P.E.P. section 1893.03(d) ("[n]ote also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions . . .").

Thus, in the present case, unity of invention exists at least as between claims drawn to polypeptides of SEQ ID NO:1 (e.g., claims 1 and 2) and claims drawn to polynucleotides which encode those polypeptides (e.g., claims 3-5 and 11-12).

Unity of Invention exists with respect to dependent claims in the same claim category as the independent claim from which they depend

Section A of M.P.E.P. section 1850, which recites the provisions of paragraph (c) of Part 1 (entitled "Instructions Concerning Unity of Invention") of Annex B (entitled "Unity of Invention") to the Administrative Instructions Under the PCT, provides:

> **A. Independent and Dependent Claims**
>
> Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By

> "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed, for example, product, process, use or apparatus or means, etc.).
>
> If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention. . . (M.P.E.P. section 1850 at section A; see also M.P.E.P. Appendix AI)

In the present case, claims 4-7, all of which depend from claim 3, are directed to compositions of matter (i.e., to products). Claims 4-7 contain all of the features of claim 3. Claims 2, 16, and 17, all of which depend from claim 1, are directed to compositions of matter (i.e., to products). Claims 2, 16, and 17 contain all of the features of claim 1. Furthermore, claim 1 is itself dependent on claim 3, and claim 1 contains all of the features of claim 3. Therefore, since both claims 1 and 3 are directed to compositions of matter (i.e., to products), there is unity of invention as between claim 1 and claim 3.

Thus, it is improper to restrict claims 1, 2, 16, and 17 from claims 3-7, as the Patent Office has done. Therefore, Applicants respectfully request that the Examiner withdraw the Restriction Requirement at least as to the composition of matter claims, and that at least those claims be considered together in a single application.

Unity of Invention exists as between all of Applicants' claims

M.P.E.P. section 1850 provides:

> Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical feature" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art. The determination is made based on the contents of the claims as interpreted in light of the description and drawings. Annex B also contains examples concerning unity of invention.

M.P.E.P. section 1893.03(d) similarly provides:

> A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at

> least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. For example, a corresponding technical feature is exemplified by a key defined by certain claimed structural characteristics which correspond to the claimed features of a lock to be used with the claimed key. Note also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions as amended July 1, 1992 contained in Appendix AI of the MPEP.

In the present case, unity of invention exists among all of Applicants' claims. The sequences of the claimed polypeptides and the sequences of the claimed polynucleotides encoding those polypeptides are corresponding technical features which are common to all of Applicants' claims. These corresponding technical features serve to technically interrelate all of Applicants' claims, and define the contribution over the prior art made by each of them. Thus, Applicants' claims are linked to form a single general inventive concept, and Applicants are therefore entitled to prosecute all of their pending claims in a single national stage application.

<u>The sequences of the claimed polypeptides, and of the claimed polynucleotides encoding those polypeptides, are corresponding technical features that are common to all of Applicants' claims, and serve to technically interrelate them</u>

Applicants' claims recite *inter alia* polypeptides of SEQ ID NO:1, polynucleotides encoding those polypeptides (including polynucleotides of SEQ ID NO:3), and polynucleotides comprising SEQ ID NO:4. The sequences of the claimed polypeptides and of the corresponding polynucleotides are common to all of Applicants' claims, given that each claim refers to one or both either explicitly or implicitly (by virtue of depending from a claim which makes explicit reference to the sequences of the claimed polypeptides or the claimed polynucleotides).

Moreover, the sequences of the claimed polypeptides and of the corresponding polynucleotides serve to technically interrelate all of Applicants' claims. Applicants' composition of matter claims (e.g., claims 1-7, 10-12, 16, 17, and 28-30) are drawn to either the polypeptides or polynucleotides themselves (e.g., claims 1 and 2, drawn to polypeptides; and claims 3-5, 11, 12, and 28, drawn to polynucleotides), to compositions of matter which comprise the polypeptides or polynucleotides as one

element (e.g.; claims 6 and 29, drawn to recombinant polynucleotides; claims 7 and 30, drawn to transformed cells; and claims 16 and 17, drawn to compositions), or to compositions of matter wherein the sequences of the claimed polypeptides functionally limit the claimed subject matter (e.g., claim 10, drawn to an antibody which specifically binds to a polypeptide of claim 1).

In Applicants' method claims (e.g., claims 9, 13-15, 19, 22, 25-27, 32, and 33), the claimed polypeptides or polynucleotides serve as either the product of the claimed method (e.g., claim 9, drawn to methods of producing the claimed polypeptides) and/or as a reagent for performing the method (e.g., claim 32, drawn to methods of using the claimed polynucleotides to produce polypeptides; claims 13-15, drawn to methods of detecting the claimed polynucleotides; claims 19, 22, 25, and 26, drawn to methods of using the claimed polypeptides in screening assays; and claims 27 and 33, drawn to methods of using the claimed polynucleotides to screen for compounds that alter expression of the polynucleotides).

Therefore, the sequences of the claimed polypeptides and of the claimed polynucleotides are corresponding technical features which are common to all of Applicants' claims. These corresponding technical features serve to technically interrelate all of Applicants' claims. As such, Applicants' claims are linked to form a single general inventive concept, and Applicants are thus entitled to prosecute all of their pending claims in a single national stage application. Withdrawal of the restriction requirement is therefore respectfully requested.

In the event that the Patent Office does not apply the Unity of Invention standard to this national stage application, Applicants note that claims directed to methods of using the claimed polynucleotides for producing polypeptides (e.g., claim 9), for detecting polynucleotides by hybridization (e.g., claims 13-15), and for screening for compounds that alter expression of the polynucleotides (e.g., claim 27), could and should be examined together with the product claims from which they depend, per the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)" which sets forth the rules, upon allowance of product claims, for rejoinder of process

claims covering the same scope of products. Applicants presume these method claims will be rejoined, upon determining allowability of the product claims from which they depend.

It is also submitted that claims 1, 2, 16, and 17, drawn to polypeptides of the invention, could be examined along with the polynucleotide claims without undue burden on the Examiner. A search for prior art to determine the novelty of the polynucleotides would substantially overlap with a search of the prior art to determine the novelty of the polypeptides encoded by the polynucleotides.

It is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. The polynucleotides encoding the polypeptides of SEQ ID NO:1 (including the polynucleotides of SEQ ID NO:3), and polynucleotides of SEQ ID NO:4, are alternatives of a similar nature in that all of the claimed polynucleotide sequences encode sorting nexin proteins. As such, the claimed polynucleotides share the common property/activity of encoding polypeptides which have sorting nexin activity. In addition, the polynucleotides of the instant invention share a common structure in that they are all polynucleotide molecules. Furthermore, the claimed polynucleotides share a common utility in, for example, toxicology studies based on expression profiling.

Applicants reserve the right to prosecute non-elected subject matter in subsequent divisional applications.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact the undersigned at (650) 621-8581.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108**.

Respectfully submitted,

INCYTE CORPORATION

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